



[Billing Code 4140-01-P]

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

Draft Office of Health Assessment and Translation Approach for Systematic Review and Evidence Integration for Literature-Based Health Assessments – February 2013; Request for Comments; Notice of a Meeting

**SUMMARY:** The National Toxicology Program (NTP) requests public comments on the Draft Office of Health Assessment and Translation (OHAT) Approach for Systematic Review and Evidence Integration for Literature-Based Health Assessments – February 2013 (available at <http://ntp.niehs.nih.gov/go/38138>). The NTP also plans to release two protocols to illustrate the application of this framework. These documents were prepared by the OHAT, Division of NTP, National Institute of Environmental Health Sciences (NIEHS). The NTP will hold a public web-based, informational meeting during the public-comment period to provide an overview of the framework, describe the contents in the case-study protocols, and respond to questions from the public on any of the documents.

### DATES:

*Public Comment Submissions:* Deadline is June 11, 2013.

Document Availability: Draft OHAT Approach – February 2013 will be available by February 26, 2013, and case-study protocols should be available on April 2, 2013, at <http://ntp.niehs.nih.gov/go/38673>.

Registration for public, web-based, informational meeting: Deadline is April 16, 2013.

Meeting: April 23, 2013, 12:00-4:00 p.m. Eastern Daylight Time (EDT). The meeting may end earlier depending on the number of registered participants and will be cancelled if there are no registered participants by close of business on April 16, 2013. Registrants will receive information by email to access the web-based meeting on or before April 19, 2013.

#### ADDRESSES:

Agency Website: The Draft OHAT Approach – February 2013, protocols, registration for web-based meeting, and public comments are at <http://ntp.niehs.nih.gov/go/38673>.

Public Comment Submissions: Email: [andrew.rooney@nih.gov](mailto:andrew.rooney@nih.gov) or submit on-line at <http://ntp.niehs.nih.gov/go/38673>.

TTY users should contact the Federal TTY Relay Service at (800) 877-8330. Requests must be made at least 5 business days in advance of the web-based meeting.

FOR FURTHER INFORMATION CONTACT: Dr. Andrew Rooney, Deputy Director, OHAT, Division of NTP, NIEHS, P.O. Box 12233, K2-04, Research Triangle Park, NC 27709. Phone: 919-541-2999, Fax: 301-480-3299, Email: [Andrew.Rooney@nih.gov](mailto:Andrew.Rooney@nih.gov).  
Hand Deliver/Courier address: 530 Davis Drive, Room K2154, Morrisville, NC 27560.

## SUPPLEMENTARY INFORMATION:

### **Background:**

The OHAT, Division of NTP, NIEHS, has led an effort for the NTP to develop an approach for carrying out literature-based health assessments that incorporates systematic review methodology. Systematic review and plans for developing the approach were introduced at the NTP Board of Scientific Counselors (BSC) meeting on June 21 – 22, 2012. A BSC working group reviewed an earlier draft of the approach (then called the draft NTP Approach) at a meeting on August 28 – 29, 2012, and provided a draft report with recommendations to the BSC at its meeting on December 11, 2012; the report was unanimously accepted by the BSC. Information, presentations, and minutes (when available) from the June and December meetings are available at <http://ntp.niehs.nih.gov/go/9741>.

The NTP prepared the “Draft OHAT Approach for Systematic Review and Evidence Integration for Literature-based Health Assessments – February 2013,” (Draft OHAT Approach – February 2013) taking into consideration input from the BSC working group, the BSC, and the public (available at <http://ntp.niehs.nih.gov/go/38673>). The approach includes seven steps that provide a framework for incorporating systematic review and evidence integration into NTP literature-based health assessments. To assist with determining if additional refinement or revision to the Draft OHAT Approach – February 2013 might be needed, OHAT plans to apply it to two case-study evaluations. One case study will evaluate the association of bisphenol A (BPA) exposure with obesity and the other will examine the association of perfluorooctanoic acid (PFOA) or perfluorooctane sulfonate (PFOS) exposure with immunotoxicity. Prior to initiating

these evaluations, OHAT is developing protocols that include specific elements for how the seven steps in the Draft OHAT Approach – February 2013 would be carried out. The protocols on BPA exposure and obesity and PFOA or PFOS exposure and immunotoxicity should be available on April 2, 2013, at <http://ntp.niehs.nih.gov/go/38673>. Persons interested in the Draft OHAT Approach – February 2013 and the protocols are encouraged to access this website to stay abreast of the most current information.

The NTP will carefully consider the public comments on the Draft OHAT Approach – February 2013 and consider what changes, if any, might be needed. The NTP plans to present the Draft OHAT Approach – February 2013 to the NTP BSC at the meeting on June 25-26, 2013 and discuss plans to update the document based on comments. Details about this meeting will be published in the **Federal Register** and posted on the NTP website (<http://ntp.niehs.nih.gov/go/165>).

#### **Request for Comments:**

The NTP invites public comments on the Draft OHAT Approach – February 2013. Two protocols are being released to illustrate application of this framework: BPA exposure and obesity and PFOA or PFOS exposure and immunotoxicity. The deadline for submission of public comments is June 11, 2013. Comments will be posted on the NTP website <http://ntp.niehs.nih.gov/go/38668> and persons submitting them will be identified by their name and affiliation and/or sponsoring organization, if applicable. Public comments can be submitted on-line or by email (see ADDRESSES, Public Comment Submissions). Persons submitting written comments should include their

name, affiliation (if applicable), phone, email, and sponsoring organization (if any) with the document.

### **Web-based Informational Meeting:**

The NTP will hold a public, web-based, informational meeting on April 23, 2013, 12:00-4:00 p.m. EDT to provide an overview of the Draft OHAT Approach – February 2013, describe the contents in the two case-study protocols, and respond to questions from the public on any of the documents. The meeting will be interactive and opportunities will be provided for members of the public to ask NTP staff specific questions that may assist in their review or understanding of the Draft OHAT Approach – February 2013. The deadline for registration for the webinar is April 16 at <http://ntp.niehs.nih.gov/go/38673>, and the event will be cancelled if there are no registered participants by close of business that day. Registrants will receive information by email to access the web-based meeting on or before April 19, 2013.

### **Background Information on OHAT:**

OHAT was established to serve as an environmental health resource to the public and regulatory and health agencies (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3094430>). This office conducts evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as "substances") cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels. OHAT also organizes workshops or state-of-the-

science evaluations to address issues of importance in environmental health sciences. OHAT assessments are published as NTP Monographs. Information about OHAT is found at <http://ntp.niehs.nih.gov/go/ohat>.

Dated: February 19, 2013

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